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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,937	07/31/2001	Charles Joel Arntzen	P00245USF	4815

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DES MOINES, IA 50309-2721

EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/918,937	ARNTZEN ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-87* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

) ☐ Notice of References Cited (PTO-892)

) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed July 31, 2001 has been entered.

Claims 73-100 are not cancelled as requested because only claims 1-72 were filed and pending upon entry of the preliminary amendment filed July 31, 2001.

Claims 101-115 are newly added, and are renumbered as claims 73-87 in accordance with rule 1.126.

Claims 1-87 are pending.

The restriction requirement mailed March 26, 2003 is hereby withdrawn in favor of the modified restriction requirement set forth below.

Supplemental Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 15-20, drawn to a viral immunogen and a vaccine, classified in class 424, subclass 189, for example.

II. Claims 8-14 and 21-27, drawn to a transgenic plant and a food, classified in class 800, subclass 278, for example.

III. Claims 28-45, drawn to a plasmid vector and a DNA fragment, classified in class 536, subclass 23.4, for example.

IV. Claims 46-47, drawn to a method for constructing a transgenic plant cell, classified in class 435, subclass 468, for example.

V. Claims 48-66, drawn to a method for producing a vaccine, classified in class 800, subclass 288, for example.

VI. Claims 67-70, drawn to a methods of administering a vaccine, classified in class 604, subclass 19, for example.

VII. Claim 71, drawn to a method of administering an edible portion of a transgenic plant, and a method of producing and administering an oral vaccine, classified in class 424, subclass 204.1, for example.

VIII. Claim 72, drawn to a method of producing and administering an oral vaccine, classified in class 435, subclass 320.1, for example.

IX. Claims 73-76 and 78-87, drawn to a vector for transforming a plant comprising a DNA sequence encoding a recombinant viral antigen protein, said protein being antigenic to an animal, classified in class 435, subclass 320.1.

X. Claim 77, drawn to a vector for transforming a plant comprising a DNA sequence encoding a recombinant viral antigen protein, said protein being antigenic to a human or an animal, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Invention I and inventions III, IV and VII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The protein immunogen and vaccine of invention I are structurally and functionally distinct from the nucleic acids of inventions III and IX-X. Additionally, the methods of inventions IV and VII-VII do not require the use of the protein immunogen and vaccine of invention I in any method step.

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because claim 8 is directed to a transgenic plant expressing any recombinant viral immunogen derived from any mammalian virus, indicating that the combination does not rely upon the specific details of the subcombination for its patentability. The subcombination has separate utility such as for a method of immunization or an immunoassay method.

Inventions V and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the vaccine can be made by another and materially different process, such as by chemical synthesis.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as a method of administering a vaccine to a non-mammalian animal, a bird, for example.

Invention II and inventions VI and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The protein transgenic plant and food of invention II are structurally and functionally distinct from the nucleic acids of inventions IX-X. Additionally, the method of invention VI does not require the use of the transgenic plant and food of invention II in any method step.

Inventions II and III and are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because claim 8 is directed to a transgenic plant expressing any recombinant viral immunogen derived from any mammalian virus, and claim 21 is directed to a food comprising at least a portion of any transgenic plant expressing any recombinant viral immunogen, indicating that the combination does not rely upon the specific details of the subcombination for its patentability. The subcombination has separate utility such as for a hybridization method.

Inventions IV and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the

transgenic plant can be made by another and materially different process, such as by whole plant transformation or by breeding.

Invention II and inventions V, VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic plant can be used in a materially different process of using that product, such as a breeding method.

Invention III and inventions VI-VII and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The plasmid vector and DNA fragment of invention III are structurally and functionally distinct from the nucleic acids of inventions IX-X. Additionally, the methods of inventions VI-VII do not require the use of the plasmid vector and DNA fragment of invention III in any method step.

Invention III and inventions IV, V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the plasmid or DNA fragment can be used in a materially different process of using that product, such as a hybridization method.

Invention IV and inventions V-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The method of invention IV requires the use of different components and different method steps than the methods of inventions V-VIII. Additionally, the method of invention IV does not require the use of the vectors of inventions IX-X in any method steps.

Invention V and inventions VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The method of invention V requires the use of different components and different method steps than the methods of inventions VI-VIII. Additionally, the method of invention V does not require the use of the vectors of inventions IX-X in any method steps.

Invention VI and inventions VII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The method of invention VI requires the use of different components and different method steps than the methods of inventions VII-VIII. Additionally, the method of invention VI does not require the use of the vectors of inventions IX-X in any method steps.

Invention VII and inventions VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The method of invention VII requires the use of different components and different method steps than the method of invention VIII. Additionally, the method of invention VII does not require the use of the vectors of inventions IX-X in any method steps.

Invention VIII and inventions IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The method of invention VIII does not require the use of the vectors of inventions IX-X in any method steps.

Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The vector of invention IX encodes a recombinant viral antigen protein which is antigenic to an animal only, whereas the vector of invention X encodes a recombinant viral antigen protein which is antigenic to both humans and animals. Furthermore, the vector of invention IX includes sequences encoding a recombinant viral antigen protein obtained from TGEV, which sequences are not included in the vector of invention X.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and the

requirement for different areas of search, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins Cynthia Collins 4/20/04